Instructions for Use
SynFrame Instruments

This instruction for use is not intended for distribution in the USA.

Not all products are currently available in all markets.

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Instructions for Use

SynFrame Instruments

Devices in scope:

03.609.004	03.609.212	03.609.612	387.374
03.609.006	03.609.304	03.609.810	387.375
03.609.008	03.609.305	03.609.813	387.376
03.609.010	03.609.306	03.609.816	387.377
03.609.012	03.609.307	03.609.819	387.378
03.609.014	03.609.308	03.609.910	387.379
03.609.016	03.609.310	03.609.913	387.391
03.609.018	03.609.312	03.609.916	387.392
03.609.020	03.609.404	03.609.919	387.393
03.609.024	03.609.405	387.333	387.394
03.609.025	03.609.406	387.334	387.395
03.609.026	03.609.407	387.335	387.396
03.609.027	03.609.408	387.336	387.397
03.609.028	03.609.410	387.337	387.398
03.609.030	03.609.412	387.338	387.399
03.609.032	03.609.504	387.343	387.451
03.609.034	03.609.505	387.344	387.452
03.609.036	03.609.506	387.345	399.201
03.609.038	03.609.507	387.346	399.202
03.609.040	03.609.508	387.347	399.203
03.609.105	03.609.510	387.353	399.209
03.609.107	03.609.512	387.356	399.211
03.609.204	03.609.604	387.358	399.212
03.609.205	03.609.605	387.361	399.213
03.609.206	03.609.606	387.362	
03.609.207	03.609.607	387.365	
03.609.208	03.609.608	387.372	
03.609.210	03.609.610	387.373	

Important note for medical professionals and operating room staff: These instructions for use do not include all the information necessary for selection and use of a device. Please read the instructions for use and the Synthes brochure "Important Information" carefully before use. Ensure that you are familiar with the appropriate surgical procedure.

Materials
Stainless Steel, Aluminium Alloy, Aluminium, PA 66 (Polyamid), Titanium Alloy, Polyphenylsulfone (PPSU).

Intended Use
SynFrame is a surgical approach and retraction system. It consists of a basic system (basic construction) and modules that are specially designed for the respective requirements and needs of various indications and/or approach techniques.

Indications/Contraindications
In case the SynFrame is used in combination with implants or instruments, please refer to the respective instruction for use for indications and contraindications and additional surgical steps.

Patient Target Group
The product is to be used with respect to the intended use, indications, contraindications and in consideration of the anatomy and health condition of the patient.

The patient target group is based upon the implant devices rather than the instruments. Specific patient target group for the implants can be found in the respective implant instructions for use.

Intended User
This device is intended to be used by qualified health care professionals e.g. surgeons, physicians, operating room staff, and individuals involved in preparation of the device. All personnel handling the device should be fully aware of the IFU and the surgical procedures, if applicable, and/or the Synthes "Important Information" brochure as appropriate.

Potential Adverse Events, Undesirable Side Effects and Residual Risks
As with all major surgical procedures, there are risks of side effects and adverse events. Possible side effects may include: adverse tissue reaction, allergy/hypersensitivity reaction, infection, damage to vital organs or surrounding structures, iatrogenic neural and vascular injury, damage to adjacent bones, disc or soft tissue. Symptoms resulting from instrument malfunction, such as bending, fragmentation, loosening and/or breakage (whole or partial).

Warnings and Precautions
- During Basic system mounting: do not lean against the basic SynFrame system. This could overload the construction, move individual parts of the SynFrame, and displace soft tissue and/or blood vessels. When moving the patient, monitor the position of the instruments in situ to avoid potential harm or dislocation of soft tissue and/or vessels.
- During assembly, check if the holding base is firmly affixed to the guide rails of the operating table and does not move. The clamping mechanism for the holding base can damage special cover materials (such as Goretex) in certain circumstances.
- During mounting of retaining ring: The set screws are designed to be loosened but not to be removed from the rings. Removal of the set screws may cause damage to the set screws.
- During soft tissue retractors/muscle retractors mounting: the retractors can apply a relatively large force to the soft tissue and vessels. For this reason, loosen the retractors from time to time to prevent pressure necrosis.
- Always align the retractor directly with the direction of pull of the guide rod so that the entire width of the retractor serves as a seat for the soft tissue.
- The pointed edge of the retractor may never contact the soft tissue; this can cause pressure necrosis and cause burns if it unintentionally contacts the coagulation device.
- If the socket wrench is used as a lever, there is a danger of too much force being transmitted to the retractor. This can damage the retracted structures (overstretching the vessels and soft tissue). It is therefore recommendable to guide the moveable retractor with your finger. The tension can be adjusted and distributed safely for soft tissue.
- During bone lever mounting: carefully insert the bone lever into the operative site and hammer it in under visual observation. The sharp tip can cause tissue damage.
- During Light-transmitting Rod and Optics Holder mounting: together with the high-power light sources, temperatures can arise at the light-source end and instrument end of the light-transmitting rod that can cause burns.
- In addition, high-energy light can increase the tissue temperature. For this reason, avoid direct contact with tissue, and maintain a distance between the tissue and distal end of the rod of at least 10 mm when affixing the SynFrame light-transmitting rod.
- Do not place the light-transmitting rod on flammable objects such as textiles (surgical drapes).
- Never look into the end of the connected light-transmitting rod (blinding hazard).
- If SynFrame is used with high-frequency or electromedical surgical equipment, make sure that this equipment does not contact the metal parts of the SynFrame.
- The SynFrame manufacturer refers to the guidelines and instructions associated with the high-frequency or electromedical surgical device manufacturers but also recommends the use of insulating and grounding techniques.
- The SynFrame Holding Base insulated (387.346) allows grounding-free patient positioning. This product must therefore be handled with care. Any damage to this component, especially to its insulating material, may lead to loss of insulation or injury to the patient.
- Check the SynFrame Holding Base insulated (387.346) for possible damage prior to each medical application, especially with regard to damages of the insulating plastic surface such as breakage or stress cracks.
- Damaged SynFrame Holding Bases insulated (387.346) may not be used again.
- Under no circumstances must the SynFrame Holding Base be dismantled, as this can cause damage and impair its insulating properties.
- Holder for Optics (387.365) may only be used to hold optics with a shaft diameter of 10.0 or 4.0 mm, since the holding force and jaw shape are designed exclusively for optics with these diameters.
- The use of optics with differing diameters will result in damage, thereby jeopardizing the secure holding of the optic.
- To avoid damage to the optics to be held, the instrument should be checked for defects and malfunction before each use.
- Before using SynFrame Light-transmitting Rod (387.362), a thorough understanding of the principles and methods used in laser endoscopy and electrosurgical procedures is necessary to avoid shock or burn risks to patients and users as well as damages to other equipment and instruments.
- Prior to each use, check the SynFrame Light-transmitting Rod (387.362) and its accessories for any possible optical and mechanical defects, both of the surface and of the distal and proximal fiber optical end faces, to avoid the risk of injury.
- To prevent the SynFrame Light-transmitting Rod (387.362) from being damaged, avoid bending stress. This can lead to damages to the optical components and result in malfunctioning of the equipment.
- The SynFrame Light-transmitting Rod is not sterile on delivery and has to be cleaned and sterilized prior to each use. Do not use damaged or defective Light-transmitting Rods.
- Failure to observe these instructions for use may result in damage to the product or the optic to be held and/or injury to the patient.

For more information, please refer to the Synthes brochure "Important Information".

Combination of Medical Devices
Synthes has not tested compatibility with devices provided by other manufacturers and assumes no liability in such instances.

The SynFrame Holding Base matches the dimensions of the SynFrame Guiding Tube (387.343) and provides a stable construction.

SynFrame Light-transmitting Rod (387.362):
- There are numerous therapeutic vistas open for combinations with laser and High frequency (HF) surgery, pneumatic or electro-hydraulic lithotriptors. In such cases, please follow the manufacturers' operating manuals and safety instructions of devices and accessories used.
- While using the SynFrame Light-transmitting Rod (387.362) with electro-medical devices, ensure that the Body floating (BF) conditions (insulated, ground-free part) are maintained.
- The simultaneous use of Nuclear Magnetic Resonance (NMR) and the SynFrame Light-transmitting Rod (387.362) can be dangerous and lead to artefacts. Please follow the corresponding manufacturers' guidelines and safety instructions.
- The use of the SynFrame Light-transmitting Rod in combination with electro-medical devices and/or power-driven accessories for light transmitters can lead to an addition of leakage currents. Failure of one of the light sources can lead to risks for the patient or hinder the surgical procedure. Keep an additional operational light source at hand or use light sources with a substitute lamp.
- In combination with high performance light sources, the temperature of the light source and the instruments can reach levels which can cause burns. Light of high radiance energy can lead to an increased temperature in the tissue. Hence, avoid direct contact with tissue and make sure the distance of the distal end of the SynFrame Light-transmitting Rod and the tissue is at least 10 mm.

Magnetic Resonance Environment
MR Unsafe: These devices are MR unsafe according to ASTM F 2052, ASTM F 2213, ASTM F 2182.

Treatment before Device is Used
Non-Sterile Device:
Synthes products supplied in a non-sterile condition must be cleaned and steam-sterilized prior to surgical use. Prior to cleaning, remove all original packaging. Prior to steam-sterilization, place the product in an approved wrap or container. Follow the cleaning and sterilization instruction given by the Synthes brochure "Important Information".

Troubleshooting

SynFrame Light-transmitting Rod (387.362):
Checking the fiber optics
- Hold one side of the fiber optic (e.g. the distal end) in the direction of a bright ceiling lamp. For this test, do not use any cold light source. View the other side (light cable connection) holding it relatively close to the eye. The individual fibers now appear to be bright. Move the side held against the lamp. The brightness of the fibers now changes. If certain fibers remain dark, this is not a cause for concern. The intensity of illumination of the SynFrame Light-transmitting Rod decreases with an increasing rupture rate of the fibers.
- The surfaces of the light inlets and outlets must be smooth and clean. If the surfaces show certain deposit layers, or if rough fibers can be felt or are withdrawn, illumination might be inadequate. If the SynFrame Light-transmitting Rod is used or prepared in this condition, it is likely to be further damaged.
- Send the SynFrame Light-transmitting Rod to the manufacturer for an inspection if the fiber optics is damaged.

Defect	Possible cause	Possible solution
Too little illumination	dirty fiber-optic surfaces (figure 2, ❶ and ❷)	clean the fiber-optic surfaces as per instructions (manual cleaning)
	stubborn residue, encrusting on the fiber-optic surfaces	remove residues as per instructions/ check water quality
	wrong light cable connection	check whether light cable connection sits well and is connected properly
	defective fiber optic	check fiber optic as per instruction
	defective light cable or light source	check light cable connection and light source
Yellowish light	dirty fiber optic	clean fiber-optic surfaces (figure 2, ❶ and ❷). If required, send the SynFrame Light-transmitting Rod in for servicing
	dirty or defective light cable connection	check light cable connection (e.g. by illuminating a white surface)
Corrosion, formation of patches, decoloring	inadequate cleaning (e.g. protein residue)	subsequent cleaning up, if required by thorough rubbing
	inadequate rinsing of the SynFrame Light-transmitting Rod between different preparation phases (especially before sterilization)	ensure adequate rinsing between the individual preparation phases
	high chloride concentration	check water quality
	heavy metal ions and/or silicates, increased content of iron, copper manganese in water or sterilization steam	check water quality, only use de-ionized (distilled) water
	high concentration of mineral substances (e.g. calcium) or organic substances	check water quality, only use de-ionized (distilled) water
	infected or too frequently used disinfection or cleaning solutions	regularly replace the disinfection and cleaning solutions
	outside rust (e.g. through steam or preparation along with damaged or rust-prone instruments)	check maintenance systems; in case of preparation with other materials, check for material compatibility, existing damages and avoid mutual contact
	contact corrosion	avoid mutual contact with other metal components

Clinical Processing of the Device
Detailed instructions for processing implants and reprocessing reusable devices, instrument trays and cases are described in the Synthes brochure "Important Information". Assembly and disassembly instructions of instruments "Dismantling Multipart Instruments" are available on the website.

SynFrame Light-transmitting Rod (387.362)
- Cleaning can be done manually or mechanically.
- Do not clean the SynFrame Light-transmitting Rod (387.362) in an ultrasonic bath.

Manual cleaning
- Use only mild cleaning substances for dissolving the impurities. These cleaning agents have to be approved of by the manufacturer for cleaning endoscopes.
- For manual cleaning, use a soft cloth, cotton and special brushes.
- Remove dirt on the optical surfaces (see figure 2, ❶ and ❷) using cotton soaked in alcohol (70% Ethanol) or a neutral cleanser.
- After cleaning, rinse thoroughly with de-ionized (distilled) water and dry with cotton or a soft cloth to remove the last traces of impurities and residues of the cleaning agents.
- Finally dry the SynFrame Light-transmitting Rod (387.362) and the individual accessories carefully using a tissue or soft absorbent cloth.

Special instructions for manual cleaning
- The fiberoptical surfaces must not be treated using sharp objects. Generally, the SynFrame Light-transmitting Rod (387.362) must be cleaned with maximum care to avoid damage because of excessive pressure, impact, bending or letting it fall.

Mechanical cleaning
- Clean and disinfect the SynFrame Light-transmitting Rod (387.362) in suitable rinsing machines fitted with special endoscope cleaning programs.
- It is also possible to use a thermodisinfector. For mechanical procedures, ensure that the SynFrame Light-transmitting Rod (387.362) remains firmly on the instrument holder and is not damaged by other instruments.

Mechanical cleaning procedure
- Place the SynFrame Light-transmitting Rod (387.362) and the disassembled accessories in a suitable instrument carrier as prescribed by the manufacturer of the rinsing machine. Ensure that there are no rinsing shadows.
- Select the appropriate endoscope cleaning program depending on the machine load and the instructions of the manufacturer. The cleaning solutions have to be recommended for light-transmitters by the manufacturers.
- In case of mechanical cleaning, clean all residues of the rinsing program thoroughly, as there could be decoloring and formation of patches, especially with regard to a subsequent sterilisation. For the last rinsing round, use de-ionized water. This can be supported by the use of a suitable neutralization agent, which can improve the post-rinse results.

Special instructions for mechanical cleaning
- In case of extreme soiling and encrusting (e.g. coagulated blood or secretion residues), it may be necessary to further clean the SynFrame Light-transmitting Rod manually.
- Remove dirt residues on optical surfaces (see figure 2, ❶ and ❷) using cotton soaked in alcohol (70% ethanol) or a neutral cleaning agent.
- Check the water quality regularly to avoid formation of residues and corrosion.
- Do not use grease or washing agents; there may be problems with respect to compatibility with plastics or adhesives and compatible accessories (e.g. electrical wires).

Additional Device-Specific Information
- The SynFrame System is insulated by the SynFrame Holding Base (insulated) (387.346) from the grounded operation room table.
- Synthes can only provide grounding-free patient positioning if SynFrame is used in combination with the SynFrame Holding Base insulated (387.346), which must be in perfect condition.

Disposal
Devices must be disposed of as a healthcare medical device in accordance with hospital procedures.

Special Operating Instructions

Holder for Optics (387.365)

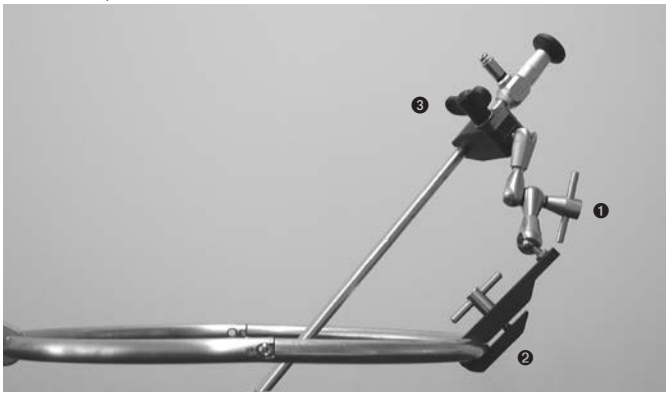

Figure 1

- Position the Holder for Optics ∅ 10.0 and 4.0 mm on the SynFrame Holding Ring 387.336
- To loosen the joint arm, turn the central locking handle ❶ (see figure 1) counterclockwise as far as it will go.
- Secure the clamp ❷ (see figure 1) to the SynFrame retaining ring, keeping the swivel arm outside the ring. This keeps the retaining arm outside the operating field.
- Insert and secure the optic in the corresponding 10.0 or 4.0 mm jaw on the black clamp ❸ (see figure 1) of the holder. Ensure that
  - the optic fits precisely into the 10.0 or 4.0 mm jaw of the black clamp and
  - the clamp is secured to the shaft of the optic as far as possible in the direction of the camera attachment.
- Position the optic in the desired position over the operating field and secure in this position by tightening the central locking handle ❶ (see figure 1) clockwise.

Notes:
- Always loosen the central locking handle ❶ (see figure 1) when repositioning the optic. The optic can be damaged (bent) if it is moved without opening the joint arm.
- The holder can be damaged if excessive force is applied when tightening the screws.

SynFrame Light-transmitting Rod (387.362)
The SynFrame Light-transmitting Rod (387.362) is used to illuminate deep cavities in the human body.

The light cable connection corresponds to the ACM Standard. Adapters for Wolf and Storz are included.

Figure 2

❶ Light exit
❷ Light cable connection ACM Standard
❸ Adapter for Wolf
❹ Adapter for Storz
❺ Fixation area for SynFrame Clamp (387.347) and Holder for Optics (387.365)

The SynFrame Clamp for Holding Rings (387.347) and Holder for Optics (387.365), which is used to connect the Light-transmitting Rod to the SynFrame Holding Ring (387.336) and the SynFrame Half-Ring (387.337), can be attached to the SynFrame Light-transmitting Rod on the entire length of the shaft of the Light-transmitting Rod (see figure 2, ❺).

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